

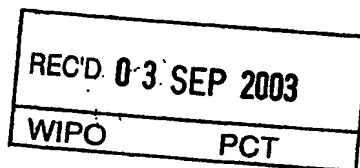


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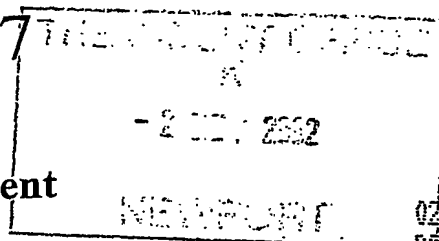
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# Patents Form 1/77

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## Request for grant of a patent



02DEC02 E767757-1 D02846  
POL/7700 0.00-0228027.9

1. Your Reference	NSP/CLD/X820		
2. Application number	0228027.9		
3. Full name, address and postcode of the or each Applicant	Advanced Pain Management Holdings PLC The Saturn Centre Challenge Way Blackburn Lancashire BB1 5QB		
Country/state of incorporation (if applicable)	Incorporated in: England & Wales		
4. Title of the invention	IMPROVEMENTS IN AND RELATING TO THE APPLICATION OF ELECTRICITY TO THE SKIN		
5. Name of agent	APPLEYARD LEES		
Address for service in the UK to which all correspondence should be sent	15 CLARE ROAD HALIFAX HX1 2HY		
Patents ADP number	190001		
6. Priority claimed to:	Country	Application number	Date of filing
	United Kingdom	0216567.8	17 Jul 2002
7. Divisional status claimed from:	Number of parent application		Date of filing
8. Is a statement of inventorship and of right to grant a patent required in support of this application?	YES		

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description	20	/
Claim(s)	5	/
Abstract	1	/
Drawing(s)	3	+ 3 <i>RL</i>

10. If you are also filing any of the following, state how many against each item

Priority documents

Translation of priority documents

Statement of inventorship and right to grant a patent (PF 7/77)

Request for a preliminary examination and search (PF 9/77)

1

Request for substantive examination (PF 10/77)

Any other documents (please specify)

PF 23/77

- 11.

We request the grant of a patent on the basis of this application.  
Signature Date

APPLEYARD LEES

29 November 2002

*Appleyard Lees*

12. Contact

Neil Parkinson- 0161 835 9655

IMPROVEMENTS IN AND RELATING TO THE APPLICATION OF  
ELECTRICITY TO THE SKIN

5 Field of the Invention

This invention relates to apparatus and methods suitable for, but not limited to, the application of electricity to the skin so as to modulate nerves electronically.

10

Background to the Invention

Today, the therapeutic and diagnostic uses of electricity in medicine are widespread. Extensive literature exists on electro-therapy, the therapeutic application of electricity, which is suitable for treatment of a range of medical conditions.

TENS (Trancutaneous Electrical Nerve Stimulation) is the application of electrical pulses via electrodes placed on the skin of a patient, so as to produce a rather short-lived, localised region of analgesia. TENS devices typically utilise pulses of width 50-500 $\mu$ s, at a current of amplitude 0-50mA, delivered at a frequency of 80-100Hz. The TENS pulse is intended to be sufficiently long in duration to excite nerve fibres in the immediate vicinity of the electrodes to cause a painless tingling at low voltage (the voltage amplitude of TENS pulses that can be tolerated by a patient tends to be limited by the level of tingling sensation that can be comfortably endured).

TSE (Trancutaneous Spinal Electroanalgesia) improves upon TENS by providing a longer-lasting form of analgesia, that

is more generalised (i.e. not limited to the immediate vicinity of the electrical stimulation). TSE is, for instance, described within US 5,776,170 which describes the original research performed in relation to this treatment.

US 5,776,170 describes how, by applying a continuous series of electrical rectangular pulses to two electrodes, analgesic effects are induced in the central nervous system. The pulses used by the TSE stimulator are typically of amplitude 180 volts (compared with 35-50 volts of the TENS device), with a relatively narrow pulse width (1-10 $\mu$ s), at frequencies of typically 600-800Hz.

Figure 1 illustrates such a continuous pulse stream. Rectangular pulses 10, 12, 14 of width W, and amplitude  $V_p$  are delivered at regular predetermined intervals T. The pulse frequency is thus  $1/T$  Hz (when T is expressed in seconds).

In traditional electro-therapy, the efficacy of treatments is generally proportional to the voltage used. However, high voltages are normally both painful to the body, and damaging to tissues. As many electro-therapy devices are powered by batteries, the high energy usage associated with high voltages is also problematic.

Clinical efficacy is also a function of the frequency at which the pulses are delivered. However, whilst the body tissues are typically unharmed by the application of high frequency pulses, the heat generated in the electrodes utilised to apply the pulses can burn the tissues of the body. For instance, US, 5,776,170 describes how voltage

has to be decreased at high frequencies so as to reduce unwanted heating effects e.g. pulses of amplitude 150 volts can be utilised at a frequency of 5kHz, whilst the voltage has to be reduced to 25 volts at 150kHz.

5

It is an aim of embodiments of the present invention to overcome, or at least alleviate, one or more problems of the prior art, whether referred to herein or otherwise.

#### 10 Statements of the Invention

In a first aspect, the present invention provides an apparatus for applying electrical pulses to a patients body by at least two electrodes at respective locations on  
15 the patients body, the apparatus comprising a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide a series of positive voltage pulses interleaved with a series of negative voltage pulses.

20

Preferably, the pulse generating unit is arranged to provide a series of alternating positive and negative voltage pulses.

25 Preferably, the pulses have a rise time from zero volts to the respective peak voltage that comprises less than or equal to 25% of the pulse width.

Preferably, the pulses have a rise time from zero volts to  
30 the respective peak voltage, the rise time being less than or equal to 4 $\mu$ s.

Preferably, the pulses have a decay time from the peak volts to zero volts that comprises at least 75% of the pulse width.

- 5 Preferably, the decay time comprises at least 95% of the pulse width.

Preferably, the pulses have a decay time from the peak voltage to zero volts that lies within the range 10 $\mu$ s to  
10 30 $\mu$ s.

Preferably, the frequency of the series of positive voltage pulses is less than 250kHz.

- 15 Preferably, the amplitude of at least one of the positive voltage pulses and the negative voltage pulses lies within the range 50 to 450 volts.

Preferably, said amplitude lies within the range 150 to  
20 250 volts.

Preferably, the amplitude of the negative voltage pulses is of substantially equal magnitude to the amplitude of the positive voltage pulses.

25

In another aspect, the present invention provides an apparatus for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body, the apparatus comprising a pulse  
30 generating unit connectable to the electrodes, the pulse generating unit being arranged to provide an intermittent series of electrical pulses.

Preferably, in said intermittent series of electrical pulses, the ratio of the time period for which no pulses are being provided to the time period for which pulses are being regularly provided is within the range 1:3 to 1:20.

5

Preferably, said ratio is approximately 1:10.

Preferably, at least one pause occurs in said intermittent series of pulses at least once every second.

10

Preferably, said pause is of duration of at least 0.5 millisecond.

15

Preferably, said series of pulses comprises a plurality of spiked pulses.

20

Preferably, said series of pulses comprises a plurality of bipolar pulses having a positive voltage peak and a negative voltage peak, with the transition time between the positive and the negative peak being at least 70% of the pulse width.

25

Preferably, said transition time is at least 95% of the pulse width.

30

Preferably, said pulses have a peak amplitude lying within the range 50-450 volts

Preferably, said pulses are delivered at a predetermined frequency, said frequency lying within the range 100Hz to 250kHz.



Preferably, the apparatus further comprises a battery for providing power to said generating unit for the generation of said pulses.

5 Preferably, the apparatus further comprises at least two electrodes arranged for connection to said generating unit, for supplying electrical pulses to respective locations on the patients body.

10 Preferably, the width of the pulses in said series lies within the range 1 to 30 $\mu$ s.

Preferably, said apparatus is for supplying electrical pulses to two or more locations on the patients body  
15 overlying the central nervous system, such that the pulses induce analgesic effects in the central nervous system, whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all.

20

In a further aspect, the present invention provides an apparatus for applying a series of electrical pulses to the body of a patient substantially as described herein with reference to Figures 2 to 6.

25

In another aspect, the present invention provides a method for applying electrical pulses to a patients body by utilising at least two electrodes at respective locations on the patients body substantially as described herein  
30 with reference to Figures 2 to 6.

### Brief Description of the Drawings

For a better understanding of the invention, and to show how embodiments of the same may be carried into effect,  
5 reference will now be made, by way of example, to the accompanying diagrammatic drawings in which:

Figure 1 illustrates a typical pulse train of a known TSE device;

10 Figure 2 illustrates an intermittent series of pulses in accordance with a first embodiment of the present invention;

Figure 3 illustrates a pulse shape in accordance with a second embodiment of the present invention;

15 Figure 4 illustrates a pulse shape in accordance with another embodiment of the present invention;

Figure 5 is a schematic diagram of a device suitable for producing pulses in accordance with an embodiment of the present invention; and

20 Figure 6 illustrates the waveforms at various points in the device shown in Figure 5.

### Detailed Description of Preferred Embodiments

25 The present inventors have realised that, by appropriately changing the waveform applied to the patient, there can be an improvement in the performance of the electrical treatment. This can be achieved either by changing the shape of each pulse in the series of pulses, or by  
30 changing the series of pulses to an intermittent series.

In a first aspect, a series of positive pulses interspaced with negative voltage pulses are used instead of the

positive voltage pulses proposed by the prior art. Surprisingly, use of such a pulse sequence allows relatively long duration pulses of relatively high voltage amplitude to be applied to a patient. This enables an  
5 increased quantity of electrical charge to be applied to the patient without unwanted side effects, thus increasing the efficacy of the treatment. Use of both positive and negative voltage pulses has been termed ENM (Electronic Nerve Modulation), and evidence suggests it provides  
10 superior treatment to TSE. For instance, ENM appears to alleviate the symptoms of viral infection, and also to decrease the period of infection.

In a further aspect, by providing an intermittent series  
15 of pulses, rather than the continuous series of pulses utilised by the prior art, high frequency electrical signals can be applied to a patient without a significant build up of heat in the electrodes. Thus, by using an intermittent series of electrical pulses, then for a given  
20 pulse frequency, higher voltages can be utilised without the electrodes burning the skin of the patient. Alternatively, for a predetermined pulse voltage amplitude, higher frequencies can be achieved without damaging tissues.

25

Further, as the number of pulses delivered in any given interval is reduced compared with a continuous series of pulses, then for a given pulse shape, amplitude and frequency, it will be appreciated that the power required  
30 is reduced. Thus, there is an improvement in battery life.

Initial trials have indicated that, despite the number of pulses being reduced due to the intermittent nature of the pulse series, clinical efficacy is not decreased compared with a similar continuous pulse series.

5

Figure 2 illustrates an intermittent series of pulses. The series in this example comprises a number of substantially uniformly sized and shaped pulses 110, 112, 114, 116, 118. The pulses are each of width  $W$ , with the spacing between each pulse in the series being normally  $T_1$ . The pulses have an amplitude of  $V_p$  volts, and in this instance are substantially rectangular in shape. The intermittent series is achieved by providing a pause of temporal duration  $T_2$ , during which there are no pulses in the sequence. Preferably, the pause is an integral number of the pulse repeat period  $T_1$  (i.e.  $T_2 = n \times T_1$ , where  $n$  is any integer). Figure 2 illustrates the case where  $T_2 = 3T_1$ , with the 3 dashed pulse shapes 216, 218, 220 indicating those pulses that have effectively been removed from the pulse sequence by the presence of the pause.

In order for nerve modulation to take place, it is desirable that the width  $W$  of the pulses lies within the range 1-30 $\mu$ s. In some instances, the pulse shape may limit the width  $W$ . For instance, a patient will normally experience a sensation if a square wave pulse wider than 10 $\mu$ s is utilised. Other, preferred waveforms are described below that allow longer width pulses to be utilised. Preferably, the pulses have a peak amplitude ( $V_p$ ) within the range of 50 to 450 volts. Preferably, the pulses are delivered at a predetermined frequency (i.e.  $1/T_1$ ) lying within the range 100Hz to 250kHz. The

intermittent series of pulses effectively comprises blocks of pulses delivered at the predetermined frequency ( $1/T_1$ ), with the blocks separated by pauses of duration  $T_2$ .

- 5 It will be appreciated that the repeat frequency of the pauses can be varied, however it is preferable that the total time period for the pause (i.e. the time period for which no pulse is being provided) compared with the average block length of the pulses (i.e. the time period  
10 for which pulses are being regularly provided) lies within the range 1:3 to 1:20. Preferably, the pauses are of duration of at least 1 millisecond (i.e.  $T_2 = 1\text{ms}$ ).

Experiments have indicated that an intermittent pause  
15 timed at 1.3 milliseconds has no effect on clinical efficacy, but it is anticipated that pauses for longer duration will also be effective, and have either no, or comparatively little effect upon the clinical efficacy. It will be appreciated that in a signal of 2500Hz, a pause  
20 of 1.3ms is over three times the length of the electronic pulse cycle (i.e. the pulse repeat time,  $T_1$ ), whilst in a signal operating at 20000Hz, it is over 25 times the length of the electronic pulse cycle.

- 25 Whilst in the above embodiment, rectangular shaped pulses have been illustrated, it has been discovered that spiked pulses (i.e. pulses with very little signal duration at maximum amplitude) are particularly effective. Such pulses preferably also have relatively fast rise and fall  
30 times. This results in the pulse width  $W$  being relatively short compared to the length of the pulse cycle (e.g.  $W$  is less than 20% of  $T_1$ , or more preferably  $W$  is less than 10% of  $T_1$ , or even less than 5% of  $T_1$ ). Spiked pulses are

believed to be particularly efficient, as they allow relatively high voltages to be utilised for a given pulse power compared with a rectangular shaped pulse.

- 5 Surprisingly, a series of positive voltage pulses interspaced with negative voltage pulses, has been found to be particularly effective. For instance, the total series of pulses delivered to the patient might comprise alternating positive and negative voltage pulses.

10

Such a series of positive and negative voltage pulses can be used as part of an intermittent series of pulses. Alternatively, the pulses can be used in a continuous series of pulses. Use of either pulse series allows a  
15 larger electrical charge to be provided to the patient than suggested by the prior art. For instance, pulses have been used with an amplitude within the range of 100 to 400 volts, without any sensations being experienced by the patient.

20

The prior art suggests that use of such high voltage pulses would lead to burning within the skin of a patient. However, it is believed that use of both positive and negative voltage pulses prevents the build up of charge  
25 within the skin, and hence the skin is less likely to burn.

The use of a fast rise time (the transition time from 0 volts to the peak voltage) of the pulses is preferable, as  
30 it is understood to lower the electrical resistance of the skin without stimulating the peripheral nerves, so that the subject (i.e. patient) feels no sensation. Further, this enables a relatively large quantity of electrical

charge to pass through the skin and tissues. Work on iontophoresis (in which a charge is applied to the skin to allow ionised particles to pass into the body of patient) has indicated that applying a voltage to the skin acts to  
5 lower the electrical resistance of the skin, the decrease in electrical resistance being proportional to the applied voltage.

It is also preferable that the voltage decays from the  
10 respective positive or negative peak voltage to zero volts, so as to ensure that the peripheral nerves are not stimulated.

Preferably, this decay occurs over a relatively long time  
15 period (e.g. up to 30 $\mu$ s), so as to maximise the electrical charge being passed to the patient.

The efficacy of the treatment appears to be related to the pulse width, with wider pulses providing more effective  
20 treatment, presumably due to the increase in the total electrical power that can be applied to the patient. By utilising positive and negative voltage pulses as described above, the pulse width can be increased dramatically compared with the pulse width of a  
25 rectangular pulse. For instance, typical known rectangular pulses are limited to a width of about 4 $\mu$ s, as longer rectangular pulses lead to a tingling feeling within the patient. However, using positive and negative voltage pulses, longer pulse widths can be comfortably  
30 utilised on a patient e.g. pulses of widths of up to 30 $\mu$ s, although preferably within the range 10 to 20 $\mu$ s, and more preferably of a width of substantially 15 $\mu$ s. This very significant discovery allows a greatly increased

electrical charge to be applied to a patient, enabling a range of therapies to be provided for the patient.

Figure 4 illustrates a portion of a sequence of alternating positive and negative voltage pulses. The positive voltage pulses 410 can be seen to be characterised by a rise time ( $W_{p1}$ ), the time taken by the pulse to transition from zero volts to the peak voltage ( $V_{pos}$ ). In this example, the pulse then immediately decays from the peak voltage  $V_{pos}$  back to zero volts, taking a time ( $W_{p2}$ ) to return to zero from the peak voltage. The approximate total width of the positive pulse  $W_p$  is thus:  
 $W_p = W_{p1} + W_{p2}$ .

After a time delay of  $T_d$  after the positive voltage pulse, a negative voltage pulse 420 is delivered. The negative voltage pulse takes a time  $W_{n1}$  to "rise" from zero volts to the peak negative voltage ( $V_{neg}$ ), and subsequently takes a time  $W_{n2}$  to fall from the peak negative voltage back to zero volts. Consequently, as the transition from the rising edge of the pulse to the falling edge of the pulse is almost instantaneous, the approximate total width of the pulse  $W_n$  is  $W_n = W_{n1} + W_{n2}$ .

In this example, positive and negative voltage pulses are alternated, with the repeat period (e.g. the time period between the start of successive positive voltage pulses) being  $T_r$ . This repeat period defines the effective frequency of the resulting pulse series (i.e. frequency =  $1/T_r$ ).

It will be appreciated that the various parameters of these pulses can vary as disclosed generally within this



specification. In this example, both the positive and negative voltage pulses are of similar shape, and of similar amplitude and duration. However, any of these parameters of these pulses can be altered. Equally, whilst a delay  $T_d$  between the pulses is shown to exist, this delay can in fact take any value from zero up to approximately 1,500 $\mu$ s. Typically, it is envisaged that each pulse will be of total width of up to 30 $\mu$ s (i.e.  $W_n \leq 30\mu s$ ,  $W_p \leq 30\mu s$ ), with the peak voltages of each pulse being within the range 50-450 volts.

Bipolar pulses (i.e. pulses that have both a positive and a negative voltage peak) have also been found to be effective. Such pulses may have a relatively fast transition from zero volts to a first peak in the pulse, and a relatively fast transition from the final peak in the pulse back to zero volts, but with a relatively gradual transition from the first peak of the pulse to the second peak of the pulse. In trials, such pulses appear to have a strong relaxation effect upon patients.

Figure 3 illustrates two such identical bipolar pulse shapes, with in this instance the first peak in the pulses being the positive voltage peak. The pulse cycle is again of length  $T_1$ , with the overall pulse width being  $W$ . The peak to peak voltage is shown as  $V_{pp}$ , with in this instance both the positive and the negative peaks being of similar amplitude (i.e. half of  $V_{pp}$ ). It will be seen that the pulse can be characterised by three time periods ( $W_1$ ,  $W_2$ ,  $W_3$ ), where  $W = W_1 + W_2 + W_3$ . The initial transition from zero volts to the first peak voltage (in this case, the rise time of pulse) is of duration  $W_1$ , the transition time from the first pulse peak to the second

pulse peak is of duration  $W_2$ , and the transition from the second pulse peak back to zero volts is of duration  $W_3$ .

It is desirable that  $W_1$  and  $W_3$  are both relatively quick compared with the overall pulse width  $W$  i.e.  $W_1 + W_3 \leq 0.3W$ , and more preferably  $W_1 + W_3 \leq 0.05W$ . In this example,  $W_1 = W_3$ . Preferably, the voltage constantly changes during the transition time  $W_2$ , and preferably the change is at a constant rate.

10

Figure 5 illustrates an apparatus 300 suitable to automatically produce an intermittent series of alternating positive and negative voltage pulses. The apparatus is powered by a battery 310, supplying a predetermined voltage of "a" Volts.

15

The apparatus can be envisaged as being in four distinct portions: a continuous fast pulse generator 330; a modulation waveform generator 320, 340; the output pulse shaping unit (360, 370, 350, 380); and the output electrodes 390a, 390b.

20

Figure 6 illustrates the waveforms at points marked A, B, C and "output" in the apparatus schematically shown in Figure 5.

25

The continuous fast pulse generator 330 is arranged to generate a continuous sequence of pulses at the desired, predetermined positive pulse output pulse frequency. In this instance, the output waveform is of similar shape to that illustrated in Figure 4, but with a negative first pulse. The waveform A is provided at one input to an OR logic gate 340.

30

The modulation waveform generator 320 is used to generate a waveform suitable for amplitude modulating the continuous fast pulse generator output, so as to obtain the desired pauses in the pulse series. In this instance, due to the particular implementation of the apparatus, the output of the modulation waveform generator is in fact the inverse of the desired amplitude modulation envelope. Consequently, the waveform B output by the modulation waveform generator 320 is at logic 1 during the desired pause interval (i.e. indicated by  $T_2$  in Figure 2), and at logic 0 for the remainder of the time.

The OR gate 340 combines the two input waveforms A, B using the logical OR operation, and outputs waveform C.

The high voltage switch 350 is operated by the output of the OR gate 340 i.e. by waveform C. The high voltage switch 350 controls the charging and discharging of capacitor 370.

The capacitor 370 charges up via the operation of a transformer 360, which acts to step up the voltage from the battery power supply 310.

25

The high voltage switch 350 operates so as to allow the capacitor 370 to be charged up to a relatively high voltage (i.e. approximately the desired peak voltage of the output pulse), with the capacitor being subsequently discharged to the output electrodes 390a, 390b. This output voltage discharge can occur through capacitor 380, which can act to differentiate the signal resulting from the discharge of capacitor 370, and so obtain the desired

waveform i.e. an intermittent series of alternating positive and negative voltage pulses.

The output voltage waveform is provided across electrodes 5 390a and 390b, before application to the body of the patient.

It will be appreciated that the apparatus shown in Figure 5 can be adapted to generate a continuous series of 10 positive and negative voltage pulses. Such a continuous pulse series generator is achieved by providing the output of the continuous fast pulse generator (A) directly to the input (C) of the high voltage switch 350. In other words, simply deleting the modulation waveform generator 320 and 15 the OR gate 340 from the apparatus results in the apparatus being suitable for providing a continuous series of bipolar pulses. If desirable, a switching arrangement could be implemented, so as to modify the apparatus shown in Figure 4 to be used for producing both an intermittent 20 series and a continuous series of pulses. In the first configuration, the connections are shown as in Figure 4. In the second, switched configuration, output A of generator 330 is connected directly to input C of high voltage switch 350, with the output from the OR gate 340 25 disconnected from the circuit.

In use, in order to obtain ENM, the electrodes are normally applied to the surface of a body overlying the central nervous system, such that analgesic effects tend 30 to be effected in the central nervous system whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all. If desired, the electrodes could be

implanted within the body, including within the skin, but it is more preferable that they are designed to simply be placed in contact with the skin surface. Typically, the electrodes are spaced apart by a distance of around 10cm, and are always over the central nervous system, irrespective of the location of the pain.

In the context of this invention, the term "central nervous system" should be interpreted to include the brain and the spinal cord, and also include the other neural tissues which may otherwise be classed as part of the peripheral nervous system, but are in close anatomical proximity to the central nervous system, such as the ganglia, autonomic or somatic, such as the dorsal root ganglia.

It will be appreciated that the above description is provided by way of example only, and that various other waveforms, and apparatus suitable for producing such waveforms, would be understood as falling within the scope of the present invention. Further, whilst the apparatus has been described in terms of being utilised for ENM, it will be appreciated that other, similar apparatus can make use of the present invention. Electrodes of such apparatus need not be located over the central nervous system when in use.

For instance, evidence suggests that locating the electrodes of a pulse generator on either side of the carotid bodies of a patient can assist in management of the cardio vascular system. Applying this type of pulse as described herein at an operating frequency of approximately 20kHz, with a peak to peak voltage of

between 250-300 volts has been shown to effect cardiovascular system, including altering the pulse rate of a patient.

- 5 Further, evidence suggests that application of this type of pulse to patients who suffer from epilepsy appears to reduce the number of epileptic fits.

10 Throughout this document, the term patient is not limited to humans, but can be understood as relating to any vertebrate species including mammals. This can include animals such as cats, dogs and horses.

15 Whilst the preferred embodiment has been described as being powered by a battery, it will be appreciated that any power source could be utilised to power the device, including a power supply comprising a transformer, and suitable for connection to a mains electricity supply.

20 The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and  
25 documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or  
30 process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each  
5 feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the  
10 foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any  
15 method or process so disclosed.

## CLAIMS:

1. An apparatus for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body, the apparatus comprising a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide a series of positive voltage pulses interleaved with a series of negative voltage pulses.
2. An apparatus as claimed in claim 1, wherein the pulse generating unit is arranged to provide a series of alternating positive and negative voltage pulses.
3. An apparatus as claimed in claim 1 or claim 2, wherein the pulses have a rise time from zero volts to the respective peak voltage that comprises less than or equal to 25% of the pulse width.
4. An apparatus as claimed in any one of the above claims, wherein the pulses have a rise time from zero volts to the respective peak voltage, the rise time being less than or equal to 4 $\mu$ s.
5. An apparatus as claimed in any one of the above claims, wherein the pulses have a decay time from the peak volts to zero volts that comprises at least 75% of the pulse width.
6. An apparatus as claimed in claim 5, where the decay time comprises at least 95% of the pulse width.



7. An apparatus as claimed in any of the above claims, wherein the pulses have a decay time from the peak voltage to zero volts that lies within the range 10 $\mu$ s to 30 $\mu$ s.

5

8. An apparatus as claimed in any one of the above claims, wherein the frequency of the series of positive voltage pulses is less than 250kHz.

10 9. An apparatus as claimed in any one of the above claims, wherein the amplitude of at least one of the positive voltage pulses and the negative voltage pulses lies within the range 50 to 450 volts.

15 10. An apparatus as claimed in claim 9, wherein said amplitude lies within the range 150 to 250 volts.

11. An apparatus as claimed in any one of the above claims, wherein the amplitude of the negative voltage  
20 pulses is of substantially equal magnitude to the amplitude of the positive voltage pulses.

12. An apparatus for applying electrical pulses to a patients body by at least two electrodes at respective  
25 locations on the patients body, the apparatus comprising a pulse generating unit connectable to the electrodes, the pulse generating unit being arranged to provide an intermittent series of electrical pulses.

30

13. An apparatus as claimed in claim 12, wherein, in said intermittent series of electrical pulses, the ratio of the time period for which no pulses are being provided

to the time period for which pulses are being regularly provided is within the range 1:3 to 1:20.

14. An apparatus as claimed in claim 13, wherein said  
5 ratio is approximately 1:10.

15. An apparatus as claimed in any one of claims 12 to 14,  
wherein at least one pause occurs in said intermittent  
series of pulses at least once every second.

10 16. An apparatus as claimed in claim 15, wherein said  
pause is of duration of at least 0.5 millisecond.

15 17. An apparatus as claimed in any one of claims 12 to 16,  
wherein said series of pulses comprises a plurality of  
spiked pulses.

18. An apparatus as claimed in any one of claims 12 to 17,  
wherein said series of pulses comprises a plurality of  
20 bipolar pulses having a positive voltage peak and a  
negative voltage peak, with the transition time  
between the positive and the negative peak being at  
least 70% of the pulse width.

25 19. An apparatus as claimed in claim 18, wherein said  
transition time is at least 95% of the pulse width.

20. An apparatus as claimed in any one claims 12 to 19,  
wherein said pulses have a peak amplitude lying within  
30 the range 50-450 volts

21. An apparatus as claimed in any one of the above  
claims, wherein said pulses are delivered at a

predetermined frequency, said frequency lying within the range 100Hz to 250kHz.

22. An apparatus as claimed in any one of the above  
5 claims, further comprising a battery for providing power to said generating unit for the generation of said pulses.

23. An apparatus as claimed in any one of the above  
10 claims, further comprising at least two electrodes arranged for connection to said generating unit, for supplying electrical pulses to respective locations on the patients body.

24. An apparatus as claimed in any one of the above  
15 claims, wherein the width of the pulses in said series lies within the range 1 to 30 $\mu$ s.

25. An apparatus as claimed in any one of the above  
20 claims, wherein said apparatus is for supplying electrical pulses to two or more locations on the patients body overlying the central nervous system, such that the pulses induce analgesic effects in the central nervous system, whilst stimulating peripheral  
25 nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all.

26. An apparatus for applying a series of electrical pulses to the body of a patient substantially as  
30 described herein with reference to Figures 2 to 6.

27. A method for applying electrical pulses to a patients body by utilising at least two electrodes at

respective locations on the patients body substantially as described herein with reference to Figures 2 to 6.

## ABSTRACT

IMPROVEMENTS IN AND RELATING TO THE APPLICATION OF  
ELECTRICITY TO THE SKIN

5

An apparatus is described for applying electrical pulses to a patients body by at least two electrodes at respective locations on the patients body. The apparatus  
10 comprises a pulse generating unit connectable to the electrodes. The pulse generating unit is arranged to provide an intermittent series of electrical pulses. Alternatively, the pulse generating unit is arranged to provide a series of positive voltage pulses interspaced  
15 with negative voltage pulses..

[Figure 2]

20

25

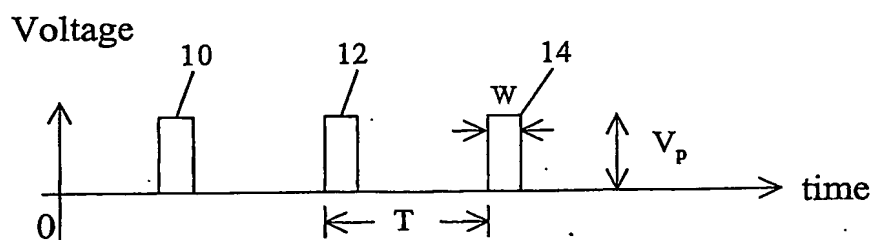


FIG. 1

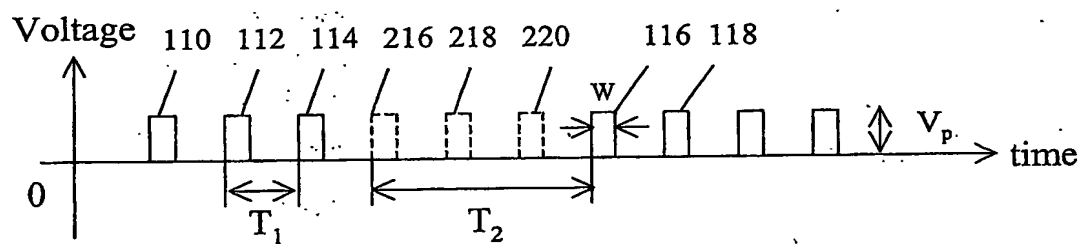


FIG. 2

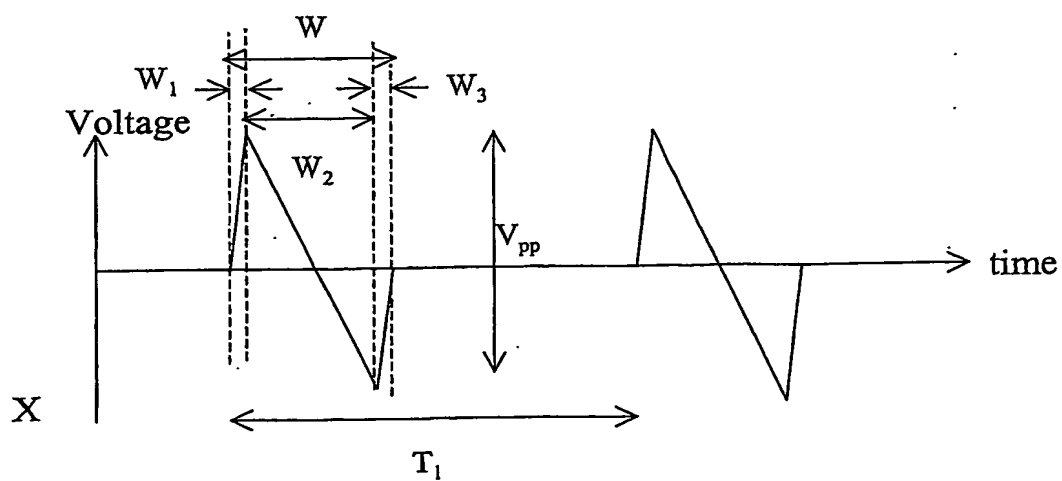


FIG. 3

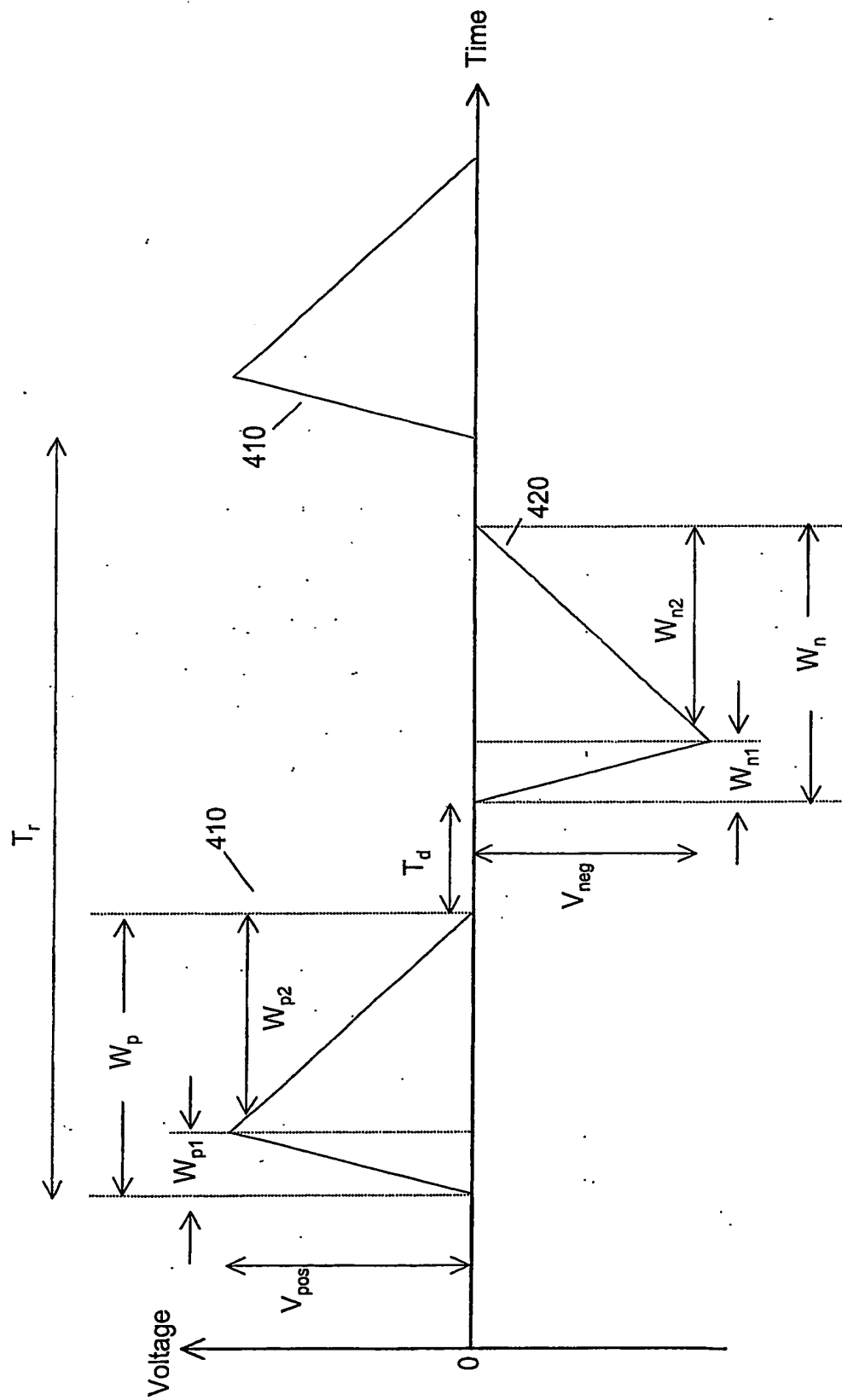


FIGURE 4

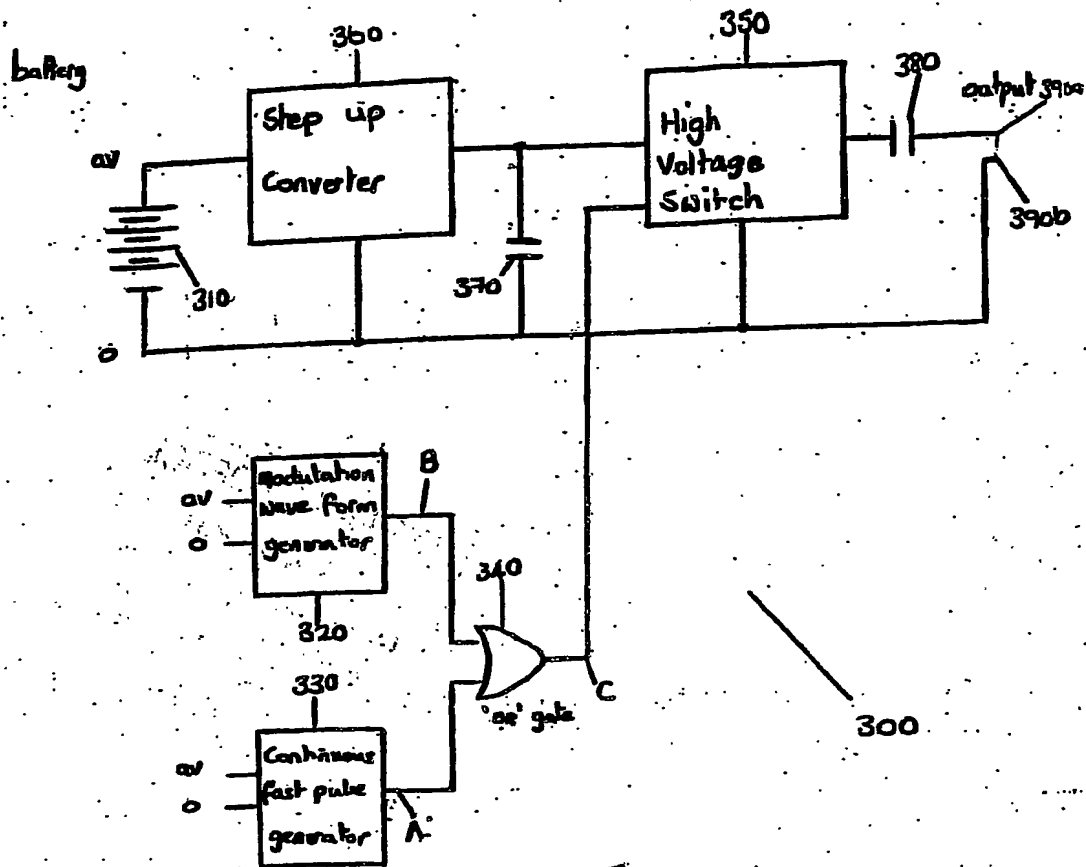


FIG. 5

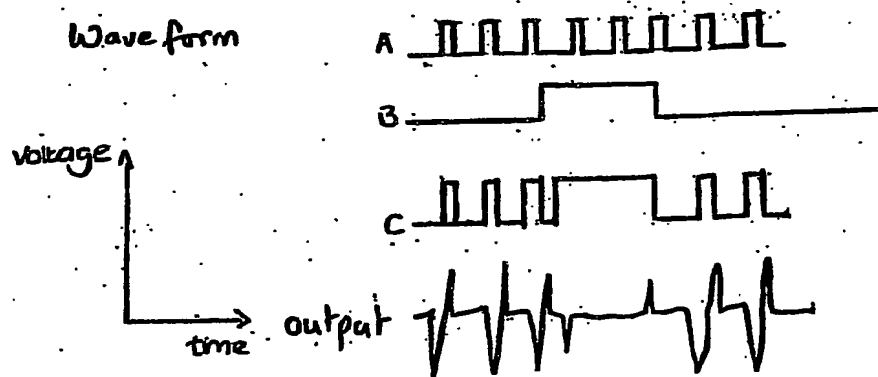


FIG. 6



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